Description

NON-FUSION SPINAL CORRECTION SYSTEMS AND METHODS

FIELD OF THE INVENTION

[0001] The present invention relates to non-fusion methods and devices for correcting spinal deformities.

BACKGROUND OF THE INVENTION

[0002] Spinal deformities, which include rotation, angulation, and/or curvature of the spine, can result from various disorders, including, for example, scoliosis (abnormal curvature in the coronal plane of the spine), kyphosis (backward curvature of the spine), and spondylolisthesis (forward displacement of a lumbar vertebra). Early techniques for correcting such deformities utilized external devices that apply force to the spine in an attempt to reposition the vertebrae. These devices, however, resulted in severe restriction and in some cases immobility of the patient. Thus, to avoid this need, several rod-based techniques were developed to span across multiple vertebrae

and force the vertebrae into a desired orientation.

[0003] In rod-based techniques, one or more rods are attached to the vertebrae at several fixation sites to progressively correct the spinal deformity. The rods are typically pre-curved to a desired adjusted spinal curvature. Wires can also be used to pull individual vertebra toward the rod. Once the spine has been substantially corrected, the procedure typically requires fusion of the instrumented spinal segments.

[0004] While several different rod-based systems have been developed, they tend to be cumbersome, requiring complicated surgical procedures with long operating times to achieve correction. Further, intraoperative adjustment of rod-based systems can be difficult and may result in loss of mechanical properties due to multiple bending operations. Lastly, the rigidity and permanence of rigid rod-based systems does not allow growth of the spine and generally requires fusion of many spine levels, drastically reducing the flexibility of the spine.

[0005] Accordingly, there remains a need for improved methods and devices for correcting spinal deformities, and in particular, there remains a need for non-fusion spinal correction systems and methods.

BRIEF SUMMARY OF THE INVENTION

[0006] The present invention provides methods and devices for treating spinal deformities. In general, the methods and devices utilize segmental fixation between several adjacent vertebrae, thus allowing each vertebrae to be repositioned independently. In one embodiment, a device is provided having a spinal anchoring element that is adapted to seat first and second spinal fixation elements at a distance spaced apart from one another, and a closure mechanism that is adapted to mate to the spinal anchoring element to lock each of the first and second spinal fixation elements in a fixed position relative to the spinal anchoring element. Each spinal fixation element can be, for example, a flexible fixation element that is preferably formed from a bioabsorbable material.

[0007] The spinal anchoring element can have a variety of configurations, but in an embodiment it includes a first recess that is adapted to receive a first spinal fixation element, and a second recess that is spaced a distance apart from the first recess and that is adapted to receive a second spinal fixation element. The first recess can be formed in a first end portion of the spinal anchoring element and the second recess can be formed in a second, opposed

end portion of the spinal anchoring element, and each recess is preferably formed in a superior surface of the anchoring element. A central portion can be formed between the first and second recesses for receiving a fastening element for mating the anchoring element to bone. In an exemplary embodiment, the central portion includes a bore extending therethrough for receiving a fastening element, such as a bone screw.

[0008] The closure mechanism that mates to the anchoring element can also have a variety of configurations, but in an embodiment it includes a central portion that is adapted to receive a locking mechanism, such as a set screw, for mating the closure mechanism to the spinal anchoring element. The closure mechanism can also include a first end portion that is adapted to lock a spinal fixation element within the first recess, and a second end portion that is adapted to lock a spinal fixation element within the second recess. In one embodiment, the first and second ends portions on the closure mechanism can include a bore formed therethrough for receiving an engagement mechanism that is adapted to extend into and engage a spinal fixation element disposed within each of the first and second recesses in the spinal anchoring element. Each en-

gagement mechanism can include, for example, a proximal, threaded portion that is adapted to mate with corresponding threads formed within the bore in the closure mechanism, and a distal pin member that is adapted to extend into a spinal fixation element positioned in each of the first and second recesses in the anchoring element. In another embodiment, the closure mechanism can include at least one protrusion formed thereon and adapted to extend into and engage a spinal fixation element disposed in each of the first and second recesses formed in the spinal anchoring element.

[0009] In yet another embodiment, the device can include a bone engaging member extending distally from the inferior surface of each of the first and second end portions of the anchoring element. The bone engaging member can be, for example, a spike that is adapted to extend into bone to prevent rotation of the spinal anchoring element.

[0010] The present invention also provides a medical system for treating spinal deformities that includes first and second flexible spinal fixation elements, and several spinal anchoring devices. Each anchoring device is adapted to mate to a vertebra and to engage each of the first and second spinal fixation elements such that the first and second

spinal fixation elements can be tensioned between each spinal anchoring device to adjust a position of each vertebra in both a sagittal plane and a coronal plate when the spinal anchoring devices are implanted in several adjacent vertebrae. The system can also include several closure mechanisms that are adapted to mate to the spinal anchoring elements to lock the first and second flexible spinal fixation elements therein.

[0011] In other aspects of the invention, a non-fusion spinal anchoring device for treating spinal deformities is provided having an anchoring element that is adapted to seat an elongate element, such as a flexible fixation element, and an engagement mechanism that is adapted to mate to the anchoring element. The engagement mechanism includes at least one protrusion formed thereon for extending into and engaging an elongate element disposed within the anchoring element to prevent sliding movement of the elongate element relative to the anchoring element. In an exemplary embodiment, the engagement mechanism includes a proximal threaded portion that is adapted to mate with corresponding threads formed on the anchoring element. The protrusion(s) preferably extends distally from the proximal threaded portion.

[0012] Methods for correcting spinal deformities are also provided. In one embodiment, the method includes the steps of implanting an anchoring device within each of a plurality of adjacent vertebrae in a spinal column, coupling first and second elongate elements to each anchoring device such that the first and second elongate elements are spaced a distance apart from one another, and locking the first and second elongate elements relative to each anchoring device to selectively tension the first and second elongate elements between each anchoring device, thereby adjusting a position of the plurality of adjacent vertebrae in the spinal column relative to one another. The vertebrae are preferably adjusted along both a sagittal plane and a coronal plane of a patient's body.

[0013] In another non-fusion method for correcting spinal deformities, a spinal anchoring device is implanted in each of a plurality of vertebrae, and first and second flexible fixation elements are fixedly coupled to each spinal anchoring device such that segmental tension is applied between each anchoring device to adjust a position of each of the plurality of vertebrae in both a coronal plane and a sagittal plane of a patient's body. Each anchoring device can include an anchoring element that is adapted to mate to a

vertebra, and a closure mechanism that is adapted to lock each of the first and second flexible fixation elements in a fixed position relative to the anchoring element.

BRIEF DESCRIPTION OF THE DRAWINGS

[0014] The invention will be more fully understood from the following detailed description taken in conjunction with the accompanying drawings, in which:

[0015] FIG. 1 is perspective view illustration of one embodiment of a spinal anchoring device in accordance with the present invention;

[0016] FIG. 2A is a side, cross-sectional view of an alternative embodiment of the spinal anchoring device shown in FIG. 1;

[0017] FIG. 2B is a side, cross-sectional view of another alternative embodiment of the spinal anchoring device shown in FIG. 1;

[0018] FIG. 2C is a side, cross-sectional view of yet another alternative embodiment of the spinal anchoring device shown in FIG. 1;

[0019] FIG. 3A is a cross-sectional view of the spinal anchoring device shown in FIG. 1 implanted in a vertebra;

[0020] FIG. 3B is perspective view illustration of several spinal anchoring systems, as shown in FIG. 1, implanted along a

portion of a human spinal column in accordance with another embodiment of the present invention;

[0021] FIG. 4A is a side, disassembled view of another embodiment of a spinal anchoring device in accordance with the present invention;

[0022] FIG. 4B is a side assembled view of the device shown in FIG. 4A;

[0023] FIG. 4C is a cross-sectional view of the device shown in FIG. 4B taken across line A-A;

[0024] FIG. 4D is a cross-sectional view of the device shown in FIG. 4B taken across line B-B;

[0025] FIG. 5 is a cross-sectional view of yet another embodiment of a spinal anchoring device having inner and outer locking mechanisms;

[0026] FIG. 6 is a cross-sectional view of another embodiment of a spinal anchoring device having two inner locking mechanisms;

[0027] FIG. 7A is a top perspective view of a portion of a spinal anchoring device having several protrusions formed thereon in accordance with yet another embodiment of the present invention;

[0028] FIG. 7B is a top view of the spinal anchoring element shown in FIG. 7A with a locking mechanism disposed

therein;

[0029] FIG. 8A is a perspective view of a deformed human spinal column having multiple spinal anchoring devices, as shown in FIGS. 4A-4C, implanted therein and mated to one another by first and second spinal fixation elements in accordance with another embodiment of the present invention;

[0030] FIG. 8B is a perspective view of the human spinal column shown in FIG. 8A after the deformity is corrected;

[0031] FIG. 9 is a perspective view of a portion of a deformed human spinal column having multiple spinal anchoring devices, as shown in FIGS. 4A-4C, implanted therein in accordance with yet another embodiment of the present invention;

[0032] FIG. 10A is a side perspective view of yet another embodiment of a spinal anchoring device in accordance with the present invention; and

[0033] FIG. 10B is a side perspective view of a spinal anchoring device in accordance with yet another embodiment of the present invention.

DETAILED DESCRIPTION OF THE INVENTION

[0034] The present invention provides methods and devices for treating spinal deformities, and in particular to non-fu-

sion methods and devices for treating spinal deformities. In general, the methods and devices utilize segmental fixation between several adjacent vertebrae, thus allowing each vertebrae to be adjusted independently. The vertebrae can be individually adjusted along both the coronal plane and the sagittal plane of the patient's body. Such a technique can be advantageous for shortening and/or halting growth of the patient's spine, however the methods and devices can be used in a variety of other spinal applications. By way of non-limiting example, the device can be used for posterior dynamization to function as a decompressive device for stenosis and/or an adjunct to an intervertebral disc to unload the facets of the vertebra.

[0035] FIG. 1 illustrates one embodiment of a spinal anchoring device 10 in accordance with the present invention. As shown, the spinal anchoring device 10 includes a spinal anchoring element 12 that is adapted to seat first and second spinal fixation elements 14a, 14b at a distance spaced apart from one another, and a closure mechanism 16 that is adapted to mate to the spinal anchoring element 12 to lock each of the first and second spinal fixation elements 14a, 14b in a fixed position relative to the spinal anchoring element 12. The device 10 can also in-

clude a fastening element 20 for mating the spinal anchoring element 12 to bone, and a locking mechanism 18 for mating the closure mechanism 16 to the spinal anchoring element 12. While not illustrated, a single fastening element can be used to attach the anchoring element to bone and to lock the closure mechanism to the anchoring element.

[0036] A person skilled in the art will appreciate that the spinal anchoring device 10 can be used with a variety of spinal fixation elements, and by way of non-limiting example, suitable fixation elements include rigid or flexible spinal rods, cables, tethers, wires, etc. The fixation elements can also be formed from a variety of materials, including, for example, stainless steel, titanium, non-absorbable polymeric braided materials, such as ultra-high molecular weight polyethylene or poly(ethylene terephthalate), absorbable polymeric braided materials, such as poly(L-lactic acid) or other high strength, slowly degrading polymers known in the art.

[0037] The spinal anchoring element 12 can have a variety of configurations, but, as stated above, it should be adapted to seat first and second spinal fixation elements 14a, 14b therein. In an exemplary embodiment, as shown, the an-

choring element 12 is in the form of a generally elongate housing having opposed superior and inferior surfaces 12s, 12i, and opposed first and second ends 12a, 12b. The inferior surface 12i is adapted to be positioned against bone when the spinal anchoring element 12 is implanted, and the superior surface 12s is adapted to seat the first and second fixation elements 14a, 14b. Accordingly, the superior surface 12s can include first and second opposed recesses 22a, 22b formed therein adjacent the opposed first and second ends 12a, 12b thereof for seating the spinal fixation elements 14a, 14b. The recesses 22a, 22b are spaced a distance apart from one another to allow the fixation elements 14a, 14b to be positioned at different locations along the patient's spinal column, as will be discussed in more detail below. Each recess 22a, 22b can vary in shape and size depending on the configuration of the fixation element 14a, 14b being disposed therein, but in an exemplary embodiment each recess 22a, 22b has a substantially convex shape. The recesses 22a, 22b also preferably extend across the superior surface 12s of the anchoring element 12 in a direction that is substantially transverse to an axis L that extends between the first and second ends 12a, 12b. As a result,

the spinal fixation elements 14a, 14b will extend in the same direction as the recesses 12a, 12b.

[0038] The spinal anchoring element 12 also preferably includes a central portion 12c that is formed between the opposed ends 12a, 12b and that is adapted to receive a fastening element 20 for mating the spinal anchoring element 12 to bone. While other techniques can be used to mate the anchoring element 12 to bone, and the anchoring element 12 can be mated at other locations on the device 10, in an exemplary embodiment the central portion 12c includes a central pathway or bore 12d extending therethrough for receiving the fastening element 20. The central bore 12d can vary in shape and size depending on the configuration of the fastening element 20. However, in an exemplary embodiment, the fastening element 20 is a bone screw having a head 20a and a threaded shank 20b, and the bore 12d includes a distal portion or recess $12d_2$ that is adapted to seat the head 20a of the bone screw 20 such the shank 20b of the bone screw 20 extends through the bore 12d. In other words, the bone screw 20 can be polyaxial relative to the anchoring element 12. In use, the bone screw 20 can be inserted through the bore 12d and threaded into bone, thereby attaching the anchoring ele-

ment 12 to bone. A person skilled in the art will appreciate that, while a polyaxial bone screw 20 is shown, the bone screw 20 can be monoaxial or it can have a variety of other configurations. Other techniques for attaching the anchoring element 12 to bone may also be used.

[0039] The spinal anchoring element 12 can also optionally include one or more bone-engaging members formed thereon and adapted to prevent rotational movement of the anchoring element 12 when the anchoring element 12 is implanted. FIG. 1 illustrates one exemplary embodiment of first and second bone-engaging members 24a, 24b formed on and extending distally from the inferior surface 12i of the anchoring element 12 at a location adjacent to the first and second ends 12a, 12b of the anchoring element 12. The bone-engaging members 24a, 24b are in the form of spikes that are adapted to extend into bone, however they can have a variety of other shapes. In use, a mallet or other device can be used to apply a force to the anchoring element 12 to impact the spikes 24a, 24b into bone at the desired implant site. The fastening element, e.g., bone screw 20, can then be inserted through the central bore 12d and threaded into bone to further secure the anchoring element 12 to the bone.

[0040] Still referring to FIG. 1, the device 10 also includes a closure mechanism 16 that is adapted to mate to the spinal anchoring element 12 to lock each of the first and second spinal fixation elements 14a, 14b in a fixed position relative to the spinal anchoring element 12. The configuration of the closure mechanism 16 can vary, and it can be formed from separate components, but more preferably it is formed from a single elongate member having a shape that is substantially similar to the shape of the anchoring element 12. As shown in FIG. 1, the closure mechanism 16 includes first and second opposed ends 16a, 16b that are configured to be juxtapositioned on the first and second opposed ends 12a, 12b of the anchoring element 12. The closure mechanism 16 also includes superior and inferior surfaces 16s, 16i. The inferior surface 16i, which is the surface that faces the superior surface 12s of the anchoring element 12, is adapted to lock the first and second fixation elements 14a, 14b within the recesses 22a, 22b formed in the anchoring element 12. Accordingly, the inferior surface 16i can include first and second recesses 26a, 26b formed therein and opposed to the first and second recesses 22a, 22b in the anchoring element 12 to facilitate engagement of the fixation elements 14a, 14b.

While the shape of each recess 26a, 26b will vary depending on the shape of each fixation element 14a, 14b, in an exemplary embodiment each recess 26a, 26b preferably has a substantially concave shape such that the opposed recesses 22a, 26a, 22b, 26b in the anchoring element 12 and the closure mechanism 16 form a substantially cylindrical cavity extending therebetween for receiving substantially cylindrical, elongate fixation elements 14a, 14b. Each recess 26a, 26b should also extend in the same direction as the recesses 22a, 22b formed in the anchoring element 12.

[0041] The closure mechanism 16 can be mated to the spinal anchoring element 12 using a variety of techniques, but in an exemplary embodiment, as shown, the closure mechanism 16 includes a central portion 16c having a central bore 16d extending therethrough for receiving a locking mechanism 18. The central bore 16d is preferably axially aligned with the central bore 12d in the anchoring element 12 to allow the locking mechanism 18 to extend through the closure mechanism 16 and to engage the anchoring element 12. While various types of locking mechanisms can be used, in an exemplary embodiment the locking mechanism 18 is a set screw 18 having a head

18a and a threaded shank 18b. The bore 16d in the closure mechanism 16 is therefore preferably adapted to seat the head 18a of the set screw, yet to allow the threaded shank 18b to pass therethrough. The bore 16d can optionally be tapered from the superior surface 16s to the inferior surface 16i to further facilitate positioning of the head 18a of the set screw 18 therein, and more preferably to allow the head 18a to seat flush or sub-flush with the superior surface 16s of the closure mechanism 16. When the head 18a is seated within the bore 16d in the closure mechanism, the threaded shank 18b of the set screw 18 extends through the bore 16d to engage the anchoring element 12. The bore 12d in the anchoring element 12 is thus preferably adapted to mate with the threaded shank 18d to allow the set screw 18 to lock the closure mechanism 16 to the anchoring element 12, thereby locking the first and second fixation elements 14a, 14b within the recesses 22a, 22b, 26a, 26b in the closure mechanism 16 and anchoring element 12. As shown in FIG. 1, a proximal portion $12d_1$ of the bore 12d in the anchoring element 12 is threaded to mate with the threaded shank 18b of the set screw 18. A person skilled in the art will appreciate that a single fastening element can be used to lock the

closure mechanism 16 to the anchoring element 12, and to also attach the anchoring element 12 to bone.

[0042] In use, when the set screw 18 is fully threaded into the bore 12d in the anchoring element 12, the closure mechanism 16 is locked to the anchoring element 12, thereby locking the first and second fixation elements 14a, 14b therebetween. Where the bone screw 20 is polyaxial, the shank 18b of the set screw 18 can be configured to contact the fastening element, e.g., bone screw 20, to lock the bone screw 20 in a fixed position relative to the anchoring element 12. In order to drive the set screw 18 into the anchoring element 12, the set screw 18 can include a mating element, such as a socket 18c, formed on or in the head 18a thereof for mating with or receiving a driver mechanism. A person skilled in the art will appreciate that a variety of other techniques can be used to lock the closure mechanism 16 to the anchoring element 12.

[0043] The spinal anchoring device 10 can also include a variety of engagement mechanisms that are adapted to engage the first and second fixation elements 14a, 14b to prevent slidable movement of the fixation elements 14a, 14b relative to the closure mechanism 16 and the anchoring element 12 when the closure mechanism 16 is locked to the

anchoring element 12. FIGS. 2A-2C illustrate various embodiments of engagement mechanisms for use with the present invention. A person skilled in the art will appreciate that a variety of other techniques can be used to facilitate locking of the first and second fixation elements 14a, 14b within the device 10.

[0044] FIG. 2A illustrates one embodiment of a spinal anchoring device 10' having protrusions 28a, 28b formed within the first and second recesses 26a', 26b' of the closure mechanism 16', and FIG. 2B illustrates another embodiment of a spinal anchoring device 10" having protrusions 30a, 30b formed within the first and second recesses 22a", 22b" of the anchoring element 12'. The size and shape of the protrusions 28a, 28b, 30a, 30b can vary, but as shown each protrusion 28a, 28b, 30a, 30b can have a substantially triangular or spiked shape. In use, the protrusions 28a, 28b, 30a, 30b extend into the spinal fixation elements 14a, 14b to engage the spinal fixation elements 14a, 14b. For example, where each fixation element 14a, 14b is formed from a flexible cable or tether, the protrusions 28a, 28b, 30a, 30b will engage the fixation element to prevent it from sliding relative to the device 10', 10". A person skilled in the art will appreciate that the closure

mechanism 16', 16" and/or the anchoring element 12', 12" can include any number of protrusions formed therein at any location.

[0045] FIG. 2C illustrates another embodiment of an engagement mechanism for preventing slidable movement of the fixation elements 14a, 14b within the device 10'''. In this embodiment, the closure mechanism 16''' includes first and second bores 34a, 34b formed therein for receiving first and second engagement mechanisms 32a, 32b, each of which is adapted to engage the spinal fixation element 14a, 14b disposed between the closure mechanism 16''' and the anchoring element 12'''. The bores 34a, 34b are preferably threaded, as shown, however they can be adapted to mate with the engagement mechanism 32a, 32b using a variety of other techniques, such as, for example, a snap-fit, an interference fit, etc. Each engagement mechanism 32a, 32b can also have a variety of configurations, but in an exemplary embodiment, as shown, each engagement mechanism 32a, 32b includes a proximal, threaded portion $32a_1$, $32b_1$ that is adapted to mate with the threaded bores 34a, 34b in the closure mechanism 16''', and a distal pin member $32a_2$, $32b_2$ that is adapted to extend into the spinal fixation element

14a, 14b positioned between the closure mechanism 16''' and the anchoring element 12'''. While the distal pin member $32a_2$, $32b_2$ preferably extends into the fixation elements 14a, 14b, where a rigid fixation element is used, the distal pin member $32a_2$, $32b_2$ can use other techniques for engaging the fixation element 14a, 14b, such as an interference fit. The device 10''' can also include, in combination with the engagement mechanisms 32a, 32b, one or more protrusions (not shown) formed therein and adapted to extend into and/or engage the spinal fixation element 14a, 14b, such as those previously described with respect to FIGS. 2A-2B.

[0046] FIGS. 3A-3B illustrate an exemplary method for correcting a spinal deformity. Referring to FIG. 3A, spinal anchoring device 10 (shown in FIG. 1) is shown in implanted in a patient's vertebra 60. The spinal anchoring element 12 is first implanted preferably by impacting the anchoring element 12 to insert the bone-engaging members or spikes 24a, 24b into the vertebra 60, thereby positioning the anchoring element 12 at the desired implant site. A fastening element, e.g., bone screw 20, can then be inserted through the bore 12d in the anchoring element 12 and threaded into the vertebra 60 to securely attach the an-

choring element 12 to the vertebra 60. The position of the anchoring element 12 relative to the vertebra 60 can vary depending on the spinal deformity being corrected. In FIG. 3A, the anchoring element 12 is implanted in the lateral aspect of the vertebra 60.

[0047] As shown in FIG. 3B, once the anchoring element 12 is securely attached to the vertebra, several additional anchoring elements 12', 12" can be implanted within adjacent vertebrae 60', 60" along the patient's spine. The location of the anchoring elements 12, 12', 12" along the spine can vary depending on the deformity being corrected. First and second spinal fixation elements, such as fixation elements 14a, 14b, are then positioned with the recess in each anchoring element 12, 12', 12" such that the fixation elements 14a, 14b span across several vertebrae 60, 60', 60". A closure mechanism 16, 16', 16" can then be applied to each anchoring element 12, 12', 12" and a locking mechanism, e.g., set screw 18, 18', 18" can be loosely threaded to each anchoring element 12, 12', 12" to loosely attach the closure mechanisms 16, 16', 16" thereto. A tension of the fixation elements 14a, 14b between each device 10, 10', 10" can then be adjusted to apply a selected segmental tension, and the tension can

be retained by tightening the locking mechanisms 16, 16', 16". The selected segmental tension can be configured to intraoperatively achieve correction immediately, or the tension can be configured such that the fixation elements 14a, 14b will asymmetrically restrict growth of the spine to achieve correction. Since the fixation elements 14a, 14b are spaced a distance apart from one another, and since the tension can be adjusted between each device 10, 10', 10", the fixation elements 14a, 14b can correct spinal deformities in both the sagittal plane and the coronal plane of the patient's body, i.e., the fixation elements 14a, 14b provide correction in all three rotational degrees of freedom.

[0048] FIGS. 4A-4D illustrate yet another embodiment of a spinal anchoring device 100 in accordance with the present invention. The spinal anchoring device 100 is similar to spinal anchoring device 10, however it is preferably only adapted to seat a single spinal fixation element 114 therein. As shown in FIG. 4A, the device 100 generally includes an anchoring element 102 that is adapted to seat a fixation element 114, and an engagement mechanism 104 that is adapted to mate to the anchoring element 102 and to engage the fixation element 114 to lock the fixation el-

ement 114 within the anchoring element 102. In this embodiment, the device 100 is particularly adapted for use with a flexible fixation element 114. However, a person skilled in the art will appreciate that the device 100 can be modified for use with rigid fixation elements. In use, multiple spinal anchoring devices 100 can be implanted in each vertebra and/or in multiple adjacent vertebrae along a patient's spinal column to provide the desired correction in one or more rotational degrees of freedom.

[0049] The anchoring element 102 can have virtually any configuration, and it can be in the form of a spinal plate, a monoaxial bone screw, a polyaxial bone screw, a hook, or any other device known in the art for anchoring a spinal fixation element to bone. In the illustrated embodiment, the anchoring element 102 is a monoaxial bone screw having a threaded, bone engaging shank 102b that is coupled to a U-shaped head 102a. The head 102a include opposed recesses $102c_1$, $102c_2$ formed therein for receiving the fixation element 114. The head 102a also preferably includes threads (not shown), or some other mating element, formed therein for mating with threads, or some other complementary mating element, formed on the engagement mechanism 104.

[0050] The engagement mechanism 104 can also have a variety of configurations as long as it is adapted to mate to the anchoring element 102 to lock the fixation element 114 therein. As shown in FIG. 4A, the engagement mechanism 104 includes a proximal, threaded portion that is adapted to mate with corresponding threads formed within the U-shaped head 102a. As previously mentioned, other techniques can be used to mate the engagement mechanism 104 to the U-shaped head 102a, including, for example, a twist-lock closure mechanism, a snap-fit, etc. The engagement mechanism 104 also includes a distal portion 104b that extends distally from the proximal, threaded portion 104a and that is adapted to at least partially extend into the fixation element 114. As shown, the distal portion 104b is in the form of a pin or spike.

[0051] FIGS. 4A-4D illustrate the device 100 with the flexible fixation element 114 locked therein. As shown, the fixation element 114 is positioned to extend through the recesses $102c_1$, $102c_2$ in the U-shaped head 102a, and the engagement mechanism 104 is threaded into the head 102a to cause the distal pin 104b to penetrate through the fixation element 114. A driver device can be used to engage a mating element, such as a socket 104(c) (FIG. 4C),

formed in the proximal threaded portion 104a of the engagement mechanism 104, and to rotate the engagement mechanism 104 to thread it into the anchoring element 102. Once the engagement mechanism 104 is fully threaded into the anchoring element 102, the fixation element 114 is locked in a fixed position such that it is prevented from moving relative to the anchoring element 102.

[0052] FIGS. 5 and 6 illustrate additional embodiments of engagement mechanisms for locking a fixation element within an anchoring element of a spinal fixation device. In the embodiment shown in FIG. 5, the spinal fixation device 200 includes inner and outer engagement mechanisms 204, 206. The inner engagement mechanism 204 is similar to engagement mechanism 104 shown in FIG. 4A as it includes a proximal threaded portion 204a that is adapted to mate with corresponding threads formed on an internal portion of the U-shaped head 202a of the anchoring element 202, and a distal portion 204b that extends distally from the proximal, threaded portion 204a and that is adapted to at least partially extend into a fixation element 214 seated within the anchoring element 202. The outer engagement mechanism 206 is also

threaded and it is adapted to mate with corresponding threads formed on an outer portion of the U-shaped head 202a of the anchoring element 202. In use, the outer engagement mechanism 206 prevents the legs of the U-shaped head 202a from splaying, thereby further locking the spinal fixation element 214 within the U-shaped head 202a.

[0053] In the embodiment shown in FIG. 6, the spinal fixation device 300 includes two inner engagement mechanisms 304, 306. The first inner engagement mechanism 304 is similar to engagement mechanism 104 shown in FIG. 4A in that it includes a proximal threaded portion 304a and a distal portion 304b that is adapted to extend into a spinal fixation element 314 seated within the spinal anchoring element 302. The proximal threaded portion 304a does not, however, mate with the U-shaped head 302a of the anchoring element 302, but rather it mates with threads formed on an inner surface of the second inner engagement mechanism 306, which in turn includes outer threads formed thereon that mate with the threads formed on the inner surface of the U-shaped head 302a. This allows the second engagement mechanism 306 to be threaded into the U-shaped head 302a to secure the

spinal fixation element 314 within the head 302a, yet to allow slidably movement of the spinal fixation element 314. The fixation element 314 can subsequently be locked within the head 302a by threading the first inner engagement mechanism 304 into the second inner engagement mechanism 306, thereby causing the distal portion 304b of the first inner engagement mechanism 304 to extend into the spinal fixation element 314. A person skilled in the art will appreciate that, while threads are shown for mating the engagement mechanisms to the anchoring element, virtually any mating technique can be used including, for example, a twist-lock, a dovetail, a snap-fit, etc.

[0054] The spinal anchoring devices can also include a variety of other features to prevent slidable movement of a fixation element relative thereto. Suitable engagement features include, for example, protrusions, such as those described with respect to FIGS. 2A-2B, knurling on the surface of each recess, non-slip coatings, and other features known in the art. FIGS. 7A and 7B illustrate yet another embodiment of a spinal anchoring device 400 having three protrusions formed thereon that are adapted to prevent slidable movement of a fixation element relative thereto. In

particular, the spinal anchoring device 400, which is similar to anchoring device 100 shown in FIG. 4A, includes a central protrusion 403 extending proximally from a substantial mid-portion of the U-shaped head 402a, and first and second smaller protrusions 405, 407 extending proximally from the recesses $402a_1$, $402a_2$ formed in the U-shaped head 402a. Each of the protrusions 403, 405, 407 is adapted to extend into a spinal fixation element (not shown) seated within the head 402a of the anchoring element 402. The spinal fixation element can then be locked within the head 402a using an engagement mechanism. As shown in FIG. 7B, the engagement mechanism 408 is threaded for mating with corresponding threads formed on the inner surface of the U-shaped head 402a. The engagement mechanism 408 also includes a central lumen 409 extending therethrough for receiving at least a portion of the central protrusion 403.

[0055] FIGS. 8A-8B illustrate one exemplary method for correcting spinal deformities using a spinal anchoring device, such as device 100 shown in FIGS. 4A-4D. In FIG. 8A, a human spinal column having a right thoraco-lumbar scoliotic deformity is shown, however the methods can be used to correct a variety of spinal deformities. Following

standard surgical procedures, the antero-lateral aspect of the thoraco-lumbar spinal vertebrae are exposed. In order to induce correction at each spinal level, several spinal anchoring elements 100(a)-(f) are implanted in one or more adjacent vertebrae, as shown. Radiographs may be obtained to determine the corrective actions needed, and thus to determine the proper placement for each anchoring element 100(a)-(f). As shown in FIG. 8A, three anchors 100(a), 100(b), 100(c) are placed in the sagittal plane on the concave side of the curve in the spinal column, and three additional anchors 100(d), 100(e), 100(f) are placed on the opposed convex side of the spinal column at a higher level than the first three anchors 100(a), 100(b), 100(c).

[0056] Next, a first fixation element 114(a) is positioned within spinal anchoring devices 100(a), 100(b), 100(c), and a second fixation element 114(b) is positioned within spinal anchoring devices 100(d), 100(e), 100(f). An engagement mechanism can then be at least partially applied to each anchoring device 100(a)-(f) to at least temporarily retain the fixation element 114(a), 114(b) therein, and preferably at least one of the engagement mechanisms on each side of the spine is fully tightened to lock the first and second

fixation elements 114(a), 114(b) to one of the anchoring devices, e.g., devices 100(a) and 100(d). The fixation elements 114(a), 114(b) can then be selectively tensioned between each anchoring device 100(a)-(f) by tightening the engagement mechanism at each level. The tension between each vertebra can vary depending on the desired correction, which can be accomplished intraoperatively by tensioning the fixation elements 114(a), 114(b) to achieve the correction immediately, and/or by allowing normal growth of the spine to achieve correction by asymmetrically restricting growth using the fixation elements 114(a), 114(b). FIG. 8B illustrates the spinal column of FIG. 8A with the deformity corrected. Once correction has been achieved, the fixation elements can optionally be cut to release the tension at one or more levels. In one embodiment, the fixation elements can be cut in a minimally invasive procedure. Cutting the fixation elements is particularly advantageous to prevent over-correction.

[0057] As noted above, the position of each fixation element along the patient's spinal column will vary depending on the spinal deformity being corrected. By way of non-limiting example, as shown in FIG. 9, to achieve correction of a scoliotic deformity in the frontal plane, both fixation

elements 114a, 114b can be placed on the convex side of the curve, with one posterior fixation element 114b and one anterior fixation element 114a. The fixation elements 114a, 114b are mated to the vertebrae by several spinal fixation devices 100a, 100b, 100c, 100d, 100e, 100f that are implanted adjacent to one another within each of several adjacent vertebrae (only three vertebrae 160a, 160b, 160c are shown for illustration purposes). Spinal fixation devices 100a, 100c, and 100e are positioned on the anterior side of the vertebrae, and spinal fixation devices 100b, 100d, and 100f are positioned on the posterior side of the vertebrae. Tension can then be applied to both the anterior and posterior fixation elements 114a, 114b by selectively fastening the fixation devices 100a, 100b, 100c, 100d, 100e, 100f to lock the fixation elements 114a, 114b therein. To correct only the frontal plane deformity, equal tension is preferably applied to both fixation elements 114a, 114b, and the degree of tension dictates how much correction is achieved intraoperatively and how much is left to take place during asymmetric growth restriction.

[0058] To achieve correction of a saggittal plane deformity in addition to correction of a scoliotic deformity, the anterior

and posterior fixation elements 114a, 114b are preferably tensioned differently. To increase lordosis, the posterior fixation element 114b is tightened more than the anterior fixation element 114a. To increase kyphosis, the anterior fixation element 114a is tightened more than the posterior fixation element 114b. Similar to correcting the scoliotic deformity, the degree of tension dictates how much correction is achieved intraoperatively and how much is left to take place during asymmetric growth restriction.

[0059] FIGS. 10A-10B illustrate additional embodiments of spinal anchoring devices 500, 600. In these embodiments, the anchoring devices 500, 600 include a combination of features from anchoring device 10, shown in FIG. 1, and from anchoring device 100 shown in FIG. 4. In particular, each anchoring device 500 includes a spinal anchoring element 512, 612 that is similar to spinal anchoring element 12 shown in FIG. 1. Anchoring elements 512, 612, however, include first and second U-shaped heads 502a, 502b, 602a, 602b formed thereon for seating first and second fixation elements. The heads 502a, 502b, 602a, 602b, which are similar to head 102 in FIG. 4, allow separate engagement mechanisms 504a, 504b, 506a, 506b to be applied thereto to secure the fixation elements separately

within the heads 502a, 502b, 602a, 602b. In FIG. 10A, the engagement mechanisms 504a, 504b are similar to engagement mechanism 104 in that they include a proximal portion $504a_1$, $504b_1$ that mates to an internal portion of the U-shaped head 502a, 502b, and a distal portion $504a_2$, $504b_2$ that is adapted to extend into a spinal fixation element to prevent slidably movement of the fixation element relative to the anchoring element 512. In FIG. 10B, the engagement mechanisms 604a, 604b are similar to engagement mechanism 408 shown in FIGS. 8A and 8B in that they each include a central lumen 609a, 609b for receiving a portion of a protrusion 603a, 603b formed within the U-shaped head 602a, 602b, and they are each adapted to threadably mate with an inner surface of each U-shaped head 602a, 602b.

[0060] In use, the separate engagement mechanisms 504a, 504b, 604a, 604b on each device 500, 600 allow first and second fixation elements disposed within the anchoring elements 512, 612 to be individually tensioned and locked relative to the anchoring element 512, 612, thereby allowing segmental tension to be created between adjacent vertebrae.

[0061] The following example serves to further illustrate the in-

vention:

[0062] Example 1

[0063] A 3mm Ultra-High Molecular Weight Polyethylene (Spectra) cable was attached to a U-shaped head of a bone screw using a set screw tightened with a torque of 5 N-m. The set screw did not include anything that penetrated into the cable. A second 3 mm Ultra-High Molecular Weight Polyethylene (Spectra) cable was attached to a U-shaped head of a bone screw using an engagement mechanism having a pin that was inserted through the cable. The engagement mechanism was tightened with a torque of 3 N-m. The force required to move each cable was tested. The cable tightened with the set screw required 32 N of force to cause 3 mm of slippage, whereas the cable tightened using the engagement mechanism required 244 N of force to cause 3 mm of slippage. Accordingly, the engagement mechanism with the pin that extended through the cable required 750% more force to move the cable.

[0064] One of ordinary skill in the art will appreciate further features and advantages of the invention based on the above-described embodiments. Accordingly, the invention is not to be limited by what has been particularly shown

and described, except as indicated by the appended claims. All publications and references cited herein are expressly incorporated herein by reference in their entirety.

[0065] What is claimed is: